In the United States Court of Federal Claims

No. 20-1319
(Filed Under Seal: November 21, 2023)
(Reissued: December 12, 2023)[1]

RONALD E. WHITE,	*
	*
Petitioner,	*
	*
v.	*
	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*

Lisa A. Roquemore, Law Office of Lisa A. Roquemore, Rancho Santa Margarita, CA, counsel for Plaintiff.

Meghan R. Murphy, U.S. Department of Justice, Civil Division, Washington, DC, counsel for Defendant.

OPINION AND ORDER

DIETZ, Judge.

Petitioner Ronald E. White ("White") seeks review of Chief Special Master ("CSM") Brian Corcoran's decision denying him compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq*. ("the Act"). White alleges that he was injured by an influenza ("flu") vaccine received on November 1, 2017. He sought compensation on October 5, 2020. The CSM denied his request, concluding that although White showed that he suffered from Guillain-Barré Syndrome ("GBS"), an injury listed on the vaccine injury table ("the Table"), the government demonstrated that a *Haemophilus influenzae* ("*H. influenzae*" or "*H. influenza*") bacterial infection was more likely the sole substantial factor causing his GBS. White contends that the CSM erred by making arbitrary and capricious findings of fact and by failing to apply the correct burden of proof to the government. Because White has not demonstrated that the CSM's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, the Court **DENIES** White's motion and **SUSTAINS** the CSM's decision denying entitlement to compensation.

[1] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, the Court issued this Opinion and Order under seal on November 21, 2023, and provided the parties fourteen days to propose redactions. *See* [ECF 46]. The parties did not propose any redactions. Accordingly, the Court reissues this Opinion and Order without redactions.

I. BACKGROUND[2]

White was born on August 1, 1947. *White*, 2023 WL 4204568, at *1. As a child, he suffered a polio infection that resulted in "chronic right lower extremity atrophy and weakness for which he wore a brace on his right leg." *Id.* On November 1, 2017, at the age of seventy, White received a flu vaccine from his primary care physician, Dr. William Larsen. *White*, 2023 WL 4204568, at *1. Dr. Larsen, a doctor with Northwest Family Physicians, administered the vaccine to White's left deltoid. *Id.* At the time, Dr. Larsen noted White's "post-polio stigmata." *Id.* (internal quotation marks omitted). Over one month later, on December 5, 2017, White visited a CVS MinuteClinic "complaining of a non-productive cough, nasal congestion, runny nose, and generalized fatigue that had lasted for two days." *Id.* White "had a temperature of 99.6 degrees, and on exam displayed bilateral middle ear effusions, mucosal edema and rhinorrhea, an irritated throat, and decreased breath sounds in his right middle lung field." *Id.* "The nurse practitioner [at the clinic] diagnosed him with a viral infection and prescribed benzonatate, a non-narcotic cough suppressant." *Id.*

Five days later, on December 10, 2017, White went to Atrium Health Harrisburg Emergency Department ("ED") complaining of a "generalized weakness" that started "approximately ten hours earlier that same day." *White*, 2023 WL 4204568, at *2. He also complained of "ongoing [upper respiratory infection ("URI")] symptoms," that started ten days before "but had not improved." *Id.* White complained of a fever that had begun "several days" prior to the ED visit, as well as "cough, wheezing, and congestion." *Id.* He indicated that although he had been taking "over-the-counter medications," he had "recently begun to experience increased weakness in his legs, and difficulty walking earlier that day that led to a fall." *Id.* At the time, White had a temperature of 97.9 degrees. *Id.*

While at the ED, White "displayed +2/5 motor strength in all extremities, and the physician could not elicit patellar reflexes." *White*, 2023 WL 4204568, at *2. "A head CT showed no acute findings, [his] chest X-ray was normal," and his "lab work revealed an elevated white blood cell count of 12.9, with elevated absolute neutrophils of 9.7." *Id.* The ED physician was concerned that White may have GBS and therefore ordered that he "be transferred to a facility that had plasmapheresis capabilities." *Id.* White's treaters "continued to report [his] concurrent URI symptoms, noting that he likely was experiencing a viral illness." *Id.*

Later that day, White's doctors transferred him to Carolinas Medical Center's intensive care unit ("ICU") "for further evaluation and treatment, and . . . for close monitoring of his respiratory status." *White*, 2023 WL 4204568, at *2. Because of "the rapid progression of his ascending paralysis," White's doctors were concerned "that he might have an underlying structural abnormality, but MRI imaging of his brain and cervical spine did not confirm the existence of such issues." *Id.* Further, his "lumbar puncture [] did not show an elevated protein level." *Id.* However, because White's doctors suspected that he had GBS based on "his clinical presentation," he "was therefore started on plasmapheresis." *Id.* Although White's cerebrospinal fluid tested negative for the presence of the herpes simplex virus, many of his "treating physicians opined or speculated that his neurologic, GBS-like symptoms were associated with

[2] The factual background is derived from the CSM's decision. *See White v. Sec'y of Health & Hum. Servs.*, 2023 WL 4204568 (Fed. Cl. June 2, 2023).

his preceding/ongoing respiratory infection." *Id.* Also, even though White "initially respond[ed] well to plasmapheresis treatment, [his] neurological condition continued to worsen, and he was intubated on December 13, 2017." *Id.* at *3. Thereafter, "[h]e was areflexic and had +1 motor strength in all extremities." *Id.* On December 14, 2017, White tested positive for "an *H. influenzae* infection."[3] *Id.* Although his blood cultures tested negative for the presence of bacteria, "[h]e had worsening chest X-ray findings in both his lungs." *Id.* White's doctors therefore gave him antibiotics intravenously for seven days and inserted a tracheostomy. *Id.*

On December 20, 2017, White's doctors transferred him from the ICU to a different unit at Carolinas Medical Center so that he could be weaned off the ventilator. *White*, 2023 WL 4204568, at *3. "His course was complicated by an ileus and two acute episodes of urinary retention." *Id.* White's doctors then tested him for GBS mimics including "arsenic poisoning, Lyme disease, HSV, neurosyphilis, and B1 deficiency." *Id.* "[N]one [of these GBS mimics] were deemed the cause of [his] condition." *Id.* During his hospitalization and following his release, however, his treaters "continued to repeat the hospital summary that [he] likely had experienced *H. influenza* pneumonia." *Id.* While hospitalized, White received seven plasmapheresis sessions.[4] *Id.* "Upon discharge, [his] differential diagnosis included GBS and *H. influenzae* pneumonia." *Id.*

After being discharged from the hospital, White's doctors transferred him to Clear Creak Nursing and Rehab Center, a "long-term acute care hospital," where his condition "continued to improve." *White*, 2023 WL 4204568, at *3. On January 24, 2018, White's doctors transferred him to Carolinas Rehabilitation Northeast, an inpatient rehabilitation facility. Although his health continued to improve there, White "remained dependent on assistance with all movement, requiring a wheelchair for ambulation and complete assistance with transfers to and from the bed and bathroom." *Id.* As of February 16, 2018, White was still unable to care for himself, and his doctors transferred him "to a skilled care facility" for additional treatment. *Id.* "Records from this time revealed mention of his prior receipt of the flu vaccine, although they do not also include treater specification of a GBS-vaccine association." *Id.*

White's doctors discharged him for the last time in May 2018, after White spent three months at another rehabilitation facility. *White*, 2023 WL 4204568, at *3. White still "required a wheelchair, hospital bed, Hoyer lift, and bedside commode for home use." *Id.* He received physical and occupational therapy at home "[t]hrough the early fall of 2018." *Id.* On May 28, 2018, during one of his initial home visits, White was "diagnosed with GBS after having a flu shot and about a week and a half of cold symptoms, which was associated with weakness and an overall decline in functional status." *Id.* (internal quotation marks omitted). Eight months later, in December of 2018, White saw his primary care physician, Dr. Catherine Norton, for an annual physical exam. *Id.* at *4. Dr. Norton noted that White was still wearing a brace on his right leg for "post-polio syndrome" and that he continued to suffer "sequelae from GBS (which the record states he developed after a flu vaccine two years prior). *Id.*

[3] A culture from a sputum sample from White's lungs revealed the presence of the infection. *White*, 2023 WL 4204568, at *3.

[4] He received the last session on December 21, 2017. *White*, 2023 WL 4204568, at *3.

On March 25, 2019, White returned to Northwest Family Physicians with "a productive cough and was diagnosed with bronchitis." *White*, 2023 WL 4204568, at *4. At the time, he was unable "to stand on his own for longer than a few seconds and required a hospital bed for a change in position, ability to prevent decubitus ulceration, and facilitate getting in and out of bed for adequate sleep." *Id.* He also required "a wheelchair for ambulation." *Id.* Five months later, in August of 2019, White had a heart attack. *Id.* He was admitted to Carolinas Medical Center from August 13 to September 5 and "underwent a coronary bypass surgery." *Id.* After surgery, White experienced "worsened left upper extremity weakness" and his doctors therefore referred him for a neurology consultation "due to concern for post-operative stroke." *Id.* Neurologist Dr. Paul Weaver examined White and noted that he had "+5/5 bilateral upper extremity and left lower extremity motor strength and +4/5 right lower extremity strength." *Id.* Dr. Weaver further noted that White "had a history of GBS secondary to *H. influenza*." *Id.* (internal quotation marks omitted). White underwent a head CT, which was "negative for acute findings." *Id.* Further, there were "no findings significant for an acute stroke, nor did [White] have worsened deficits." *Id.* Dr. Weaver recommended that White begin to wean off narcotics and engage in rehabilitation to rebuild his strength. *Id.*

In September of 2019, cardiologist Dr. Kiran Venkatesh examined White. *White*, 2023 WL 4204568, at *4. Dr. Venkatesh did not document any "musculoskeletal complaints." *Id.* Thereafter, from October 24 through December 17, 2019, White received occupational and physical therapy services at home through Bayada Home Health Care. *Id.* In 2020, Dr. Peter Nguyen, a doctor with Harrisburg Family Physicians, began treating White for diabetes. *Id.* It is unclear "from these later records" whether White continued to suffer from GBS at this time. *Id.*

On October 5, 2020, White sought compensation under the Act. *See* Pet. for Compensation [ECF 1]. He alleged that he contracted GBS from the flu vaccine. *Id.* at 1-5.[5] Although the CSM found that White "met his prima facie burden of proof for a table flu vaccine GBS claim," he also found that the government successfully showed that White's condition was caused by a factor unrelated to the vaccine—"an intercurrent *H. influenza* infection." *White*, 2023 WL 4204568, at *15. Therefore, on June 2, 2023, the CSM denied White's request for compensation. *Id.* at *19. White sought review of the CSM's decision on June 27, 2023. [ECF 36]. The government responded, [ECF 41], and White requested leave to file a reply, [ECF 42]. The Court allowed each party to file a reply, *see* [ECF 43]; however, only the petitioner did so, [ECF 42-1]. The motion is fully briefed, and the Court held oral argument on November 17, 2023. *See* [ECF 44].

II. STANDARD OF REVIEW

This Court has jurisdiction under the Act to review a special master's decision. 42 U.S.C. § 300aa-12(e)(2). In reviewing a special master's decision, this Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (B) set aside any of the findings of fact or conclusions of law of the special master found

[5] All page numbers in the petition for compensation and the parties' briefings refer to the page numbers generated by the CM/ECF system.

> to be arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)-(C).

This Court reviews a special master's findings of fact under the "arbitrary and capricious" standard, legal questions under the "not in accordance with law" standard, and discretionary rulings under the "abuse of discretion" standard. *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001). With respect to the arbitrary and capricious standard, "no uniform definition . . . has emerged," but it is "a highly deferential standard of review" such that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1527-28 (Fed. Cir. 1991); *accord Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (a decision is arbitrary and capricious only if it is "so implausible that it could not be ascribed to a difference of view"). The "not in accordance with law" standard, on the other hand, is applied without deference to legal determinations such as "[w]hether the special master applied the appropriate standard of causation . . . ." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1366 (Fed. Cir. 2013). Lastly, the abuse of discretion standard applies to the special master's evidentiary rulings, such as determinations regarding the qualification of experts and the admissibility of their testimony. *Piscopo v. Sec'y of Health & Hum. Servs.*, 66 Fed. Cl. 49, 53 (2005) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). "The [abuse of discretion standard] will rarely come into play except where the special master excludes evidence." *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); *accord Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012).

The Federal Circuit has made clear that special masters, as the finders of fact, have the responsibility to weigh the persuasiveness and reliability of evidence presented to them, and if appropriate, the credibility of testimony. *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010); *see Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) ("[T]he rules of evidence require that the trial judge determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline.") (internal quotation marks omitted). The special master has broad discretion in determining the credibility of witnesses and weighing the evidence, and these credibility determinations are "virtually unreviewable" by the reviewing court. *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In other words, the reviewing court does not reweigh the evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses because all of these matters are within the purview of the factfinder. *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1349 (Fed. Cir. 2010); *accord Loyd, Next Friend of C.L. v. Sec'y of Health & Hum. Servs.*, 2023 WL 1878572, at *2 (Fed. Cir. Feb. 10, 2023).

III. LEGAL STANDARDS

The Act was established to compensate individuals for a vaccine-related injury or death after a showing that the vaccine caused that injury or death. 42 U.S.C. § 300aa-11(a)(5)(B)(10). The Act provides two ways for a petitioner to establish causation. *Munn*, 970 F.2d at 865. First, a petitioner may demonstrate causation through a statutorily prescribed presumption by showing that the alleged injury meets the criteria listed on the Table. 42 U.S.C. § 300aa-14. Thus, "if a petitioner can establish that [he] received a listed vaccine and experienced such symptoms or injuries within the specified timeframes, [he] has met [his] prima facie burden to prove that the vaccine caused [his] injuries." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). Alternatively, if a petitioner suffered an injury listed on the Table but not within the specified time period or if a petitioner suffered an "off-Table injury," he must prove "causation-in-fact" by a preponderance of the evidence.[6] *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii); *see also Broekelschen*, 618 F.3d at 1341-42. "Causation-in-fact in the Vaccine Act context is the same as 'legal cause' in the general torts context." *de Bazan*, 539 F.3d at 1351. Thus, "the vaccine is a cause-in[-]fact when it is 'a substantial factor in bringing about the harm.'" *Id.* (quoting Restatement (Second) of Torts § 431(a)).

In *Althen*, the Federal Circuit stated a three-part test for showing causation in fact. It requires the following:

> [A petitioner must] show by a preponderance of the evidence that the vaccination brought about the injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278. Before applying the *Althen* test, however, the Court must determine whether a petitioner has shown by preponderant evidence a "medically recognized injury" that is "more than just a symptom or manifestation of an unknown injury." *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011) (explaining that "if the existence and nature of the injury itself is in dispute," then "identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation").

"Once the petitioner has established a prima facie case for entitlement to compensation and thus met [his] burden to prove causation-in-fact, the burden shifts to the government to prove "[by] a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *de Bazan*, 539 F.3d at 1352 (quoting 42 U.S.C. § 300aa-13(a)(1)(B)). Under the Act, "factors unrelated to the administration of the vaccine" may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the

[6] "This court has interpreted the 'preponderance of the evidence' standard referred to in the Vaccine Act as one of proof by a simple preponderance, of 'more probable than not' causation." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005).

petitioner's illness, disability, injury, condition, or death." 42 U.S.C.A. § 300aa-13(a)(2)(B). Significantly, while a petitioner need only demonstrate that the vaccine was a substantial factor in bringing about the alleged harm, the government must demonstrate that an unrelated factor "was the *sole* substantial factor in bringing about the injury." *de Bazan*, 539 F.3d at 1354 (emphasis added). In addition, the government's proof of alternative actual causation in fact must satisfy the same standard as the petitioner's proof of actual causation in fact in off-table cases. *Deribeaux*, 717 F.3d at 1368 (citing *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). However, if the Court finds that the government failed to prove alternative actual causation in fact, the petitioner is entitled to compensation. *de Bazan*, 539 F.3d at 1352. If the Court finds the parties' evidence to be in equipoise, the petitioner is still entitled to compensation. *Heinzelman v. Sec'y of Health & Hum. Servs.*, 2008 WL 5479123, at *19 (Fed. Cl. Dec. 11, 2008) (citing *Knudsen*, 35 F.3d at 550).

IV. ANALYSIS

White challenges the CSM's finding that his *H. influenza* infection preceded the onset of his GBS symptoms. Additionally, White asserts that the CSM improperly lowered the evidentiary burden of proof under the first and third *Althen* prongs in reaching the conclusion that the government satisfied its burden to show that White's GBS was caused by *H. influenzae*, a factor unrelated to the vaccine. For the reasons below, the Court concludes that White has not shown that the CSM's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

A. Findings of Fact

White argues that the CSM's finding that White suffered from an *H. influenzae* infection prior to hospitalization was arbitrary and capricious. Mot. for Review [ECF 36] at 45. White contends that although his medical records contain numerous references to the presence of cold and URI symptoms prior to his hospitalization, the records also document the lack of symptoms commonly associated with a cold or URI. *Id.* at 43-44. White further contends that the first indication of *H. influenza* appears on his medical record from December 17, 2017—after his hospitalization, that his *H. influenza* cultures were conducted after his hospitalization, and that "[t]he medical records seem to indicate that the *H. influenza* occurred *during* the hospital stay." *Id.* (emphasis in original). White complains that "[t]he CSM minimized all of this relevant evidence in order to find that [White], more likely, did have an ongoing *H. influenza* process in advance of the onset of the GBS." *Id.* at 45.

The Court concludes that the CSM's finding that White suffered from a *H. influenzae* infection prior to being hospitalized was rationally based upon the record evidence before him because it came from White's own statements about his condition, the notes of the various practitioners who treated White, and from White's medical test results.

The CSM describes White's condition when he went to the CVS clinic on December 5, 2017, as follows:

> [He was] complaining of a non-productive cough, nasal congestion, runny nose, and generalized fatigue that had lasted for two days . . . had a temperature of 99.6 degrees, and on exam displayed bilateral middle ear effusions, mucosal edema and rhinorrhea, an irritated throat, and decreased breath sounds in his right middle lung field.

White, 2023 WL 4204568, at *1 (citing [ECF 6-5] at 3-5 (12/5/2017 clinic notes taken by Nurse Practitioner Anita Vaughan)).

Next, the CSM stated that when White was admitted to the ED five days later, he complained "of generalized weakness that he reported had begun approximately ten hours earlier that same day. . . . [and] also noted ongoing URI symptoms that he said had begun ten days prior but had not improved." *White*, 2023 WL 4204568, at *2 (citing [ECF 6-7] at 143-45 (12/10/2017 ED notes taken by Dr. Patrick Lynch)). The CSM added that White "stated that he had a fever several days ago, cough, wheezing, and congestion, and was self-treating with over-the counter medications and prescriptions. . . . [and that h]e had a temperature of 97.9 degrees . . . ." *White*, 2023 WL 4204568, at *2 (citing [ECF 6-7] at 143-44 (12/10/2017 ED notes taken by Dr. Patrick Lynch); *id.* at 196 (12/10/2017 ED notes taken by Registered Nurse Emily K. Alexander)). Further, the CSM stated:

> Upon examination, [White] displayed +2/5 motor strength in all extremities, and the physician could not elicit patellar reflexes. . . . A head CT showed no acute findings, and [White's] chest X-ray was normal. . . . [White's] lab work revealed an elevated white blood cell count of 12.9, with elevated absolute neutrophils of 9.7. . . . Based upon these findings, the [treating] physician expressed concern about the possibility of GBS, and therefore ordered [White] to be transferred to a facility that had plasmapheresis capabilities.

White, 2023 WL 4204568, at *2 (citing [ECF 6-7] at 144-48 (12/10/2017 ED notes taken by Dr. Patrick Lynch); *id.* at 179 (12/10/2017 ED test results); [ECF 6-1] at 338 (same)). The CSM also stated that "treaters continued to report [White's] concurrent URI symptoms, noting that he likely was experiencing a viral illness," *White*, 2023 WL 4204568, at *2.[7] The CSM continued: "*[T]hroughout* [White's] hospitalization and even after his discharge, there were numerous

[7] The CSM cited [ECF 6-1] at 38 (12/11/2017 ICU notes taken by Dr. Sara Skavroneck); *id.* at 49 (12/20/2017 ICU notes taken by Dr. Sailaja Allamneni); *id.* at 146 (ICU notes taken by Dr. Robert M. Lombard, Jr.); *id.* at 154 (ICU test results and notes taken by Certified Physician's Assistant Alexandra Stewart); *id.* at 164 (12/22/2017 ICU notes taken by Dr. Allamneni); *id.* at 174 (12/21/2017 notes taken by Dr. Rahul Karamchandani and ICU test results); *id.* at 184 (12/21/2017 ICU notes taken by Dr. Allamneni); *id.* at 200 (ICU notes taken by Dr. Kwon and test results); *id.* at 205 (ICU notes taken by Dr. Rebecca E. Burkhart); *id.* at 226 (12/18/2017 ICU notes taken by Dr. Karamchandani and test results); *id.* at 228-29 (12/18/2017 ICU notes taken by Dr. Arina Ghaffari, ICU notes taken by Dr. Burkhart); *id.* at 257 (12/16/2017 ICU notes taken by Dr. Douglas W. Haden); *id.* at 268 (ICU notes taken by Dr. Scott Crane); and *id.* at 316 (ICU notes taken by Dr. Luke A. Neilans).

occasions where treaters continued to repeat the hospital summary that [he] likely had experienced *H. influenza* pneumonia." *Id.* at *3 (emphasis added).[8]

In sum, the CSM's decision shows that he considered the relevant record evidence, drew plausible inferences, and articulated a rational basis in reaching the conclusion that White's *H. influenza* infection preceded the onset of his GBS symptoms. The Court will not second guess his factual findings. *See Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992) ("[I]t is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. . . . [W]e do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.").[9]

B. Legal Conclusions

White disputes the CSM's analysis under two of the three *Althen* prongs. Specifically, White contends that the CSM improperly held that the government satisfied the first and third *Althen* prongs and therefore erroneously concluded that the government proved that White's GBS was in fact caused by *H. influenzae*. The Court begins its review of the CSM's analysis with an overview of the expert witness reports in evidence.

1. Expert Witness Reports

White's expert witness, Dr. Lawrence Steinman,[10] opined that White's GBS was caused by his flu vaccine. [ECF 22-1] at 7. According to Dr. Steinman, components of the flu vaccine White received "initiated an immune response that cross-reacted by molecular mimicry to two antigens that are known to be targeted in GBS." *Id.* at 1. Specifically, he stated that "[t]he components of the 2017-2018 influenza vaccine have molecular mimicry with myelin basic

[8] The CSM cited [ECF 6-1] at 50 (12/20/2017 ICU notes taken by Dr. Allamneni); *id.* at 83 (12/28/2017 ICU notes taken by Dr. Allamneni); *id.* at 90 (12/27/2017 ICU notes taken by Dr. Allamneni); *id.* at 102 (12/26/2017 ICU notes taken by Dr. Allamneni); *id.* at 111 (ICU notes taken by Dr. Robert M. Lombard, Jr.); *id.* at 123 (ICU notes taken by Dr. Lombard); *id.* at 146 (ICU notes taken by Dr. Lombard); *id.* at 165 (12/22/2017 ICU notes taken by Dr. Allamneni); *id.* at 185 (12/21/2017 ICU notes taken by Dr. Allamneni); and *id.* at 200 (ICU notes taken by Dr. Matt Hyoung Jin Kwon).

[9] Further, although not included by the CSM in the "Fact History" section of his opinion, the Court notes that the CSM was persuaded by the government expert's assessment of White's test results:

> Dr. Collins, who is an expert in infectious diseases, has persuasively explained that a positive blood culture is unnecessary to confirm the presence of an *H. influenza* infection and in fact would not be expected unless the infection has spread to his blood. . . . More conclusive evidence comes from sputum findings, which were positive, and the pneumonia diagnoses was further supported by chest X-ray findings and other evidence of the infection.

White, 2023 WL 4204568, at *17. Thus, the CSM's conclusion that White contracted an *H. Influenzae* infection prior to contracting GBS was also rationally based on an expert's assessment of White's condition.

[10] Dr. Steinman, who is board-certified in neurology, teaches and sees patients at Stanford University. Dr. Steinman's First Expert Report [ECF 22-1] at 2.

protein and with contactin-1." *Id.* Dr. Steinman defined molecular mimicry as follows:

> [It is] an evolutionary adaptation whereby viruses and bacteria attempt to fool the body into granting them free access. Such mimicry works by showing the immune system stretches of amino acids that look like self. For example, adenovirus type 2 has amino acid sequences like those in the crucial fragment of myelin basic protein. In responding routinely to this virus, the immune system may become primed to attack the corresponding self-component—myelin.

Id. at 10 (quoting L. Steinman, *Autoimmune Disease*, 269 SCIENTIFIC AMERICAN 106, 106-114 (1993)). Significantly, although Dr. Steinman held fast to his belief that White's GBS was caused by the flu vaccine, he conceded that "in rare circumstances H. influenza infection is associated with GBS." *Id.* at 9. In his view, however, it was unclear from the record whether White had an *H. influenzae* infection prior to getting GBS. *Id.*

The government's expert witness, Dr. Collins,[11] reached a different conclusion. She found that White's GBS was not caused by the vaccine but was instead more likely the result of an ongoing *H. influenzae* infection in his lungs. [ECF 25-1] at 3, 5. She stated: "Based on the exhibits and a review of the current literature, it is more likely than not that the influenza vaccination administered to [White] on November 1, 2017, did not cause his [GBS]." *Id.* at 6. After briefly discussing six studies,[12] she further concluded that "[t]he risk of [GBS] following the receipt of the influenza vaccine is significantly less than that following acute respiratory infection." *Id.*

Next, Dr. Collins considered the relationship between various infections and GBS. [ECF 25-1] at 8-10. Regarding the association between infections causing "acute respiratory infections" and GBS, she cited a 2007 study of 500 GBS cases taken from a United Kingdom database. *Id.* at 10.[13] About the Tam study, Dr. Collins noted the following:

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[11] Dr. Kathleen L. Collins, who is board-certified in infectious disease, teaches at the University of Michigan, and has a clinical practice. Dr. Collins' First Expert Report [ECF 25-1] at 1.

[12] Dr. Collins cited: (1) [ECF 25-6] (J. Stowe et al., *Investigation of the Temporal Association of Guillain-Barré Syndrome with Influenza Vaccine and Influenza like Illness Using the United Kingdom General Practice Research Database*, 169 AM. J. EPIDEMIOLOGY 382, 385-86 (2008)) ("Stowe"); (2) [ECF 25-7] L. Grimaldi-Bensouda et al., *Guillain-Barré Syndrome, Influenza like Illnesses, and Influenza Vaccination During Seasons with and Without Circulating A/H1N1 Viruses*, 174 AM. J. EPIDEMIOLOGY 326, 326 (2011) ("Grimaldi-Bensouda"); (3) [ECF 25-8] (S.K. Greene et al., *Guillain-Barré Syndrome, Influenza Vaccination, and Antecedent Respiratory and Gastrointestinal Infections: A Case-Centered Analysis in the Vaccine Safety Datalink*, 8 PLoS One e67185 (2013)); (4) [ECF 25-9] (C. Vellozzi et al., *Cumulative Risk of Guillain-Barré Syndrome Among Vaccinated and Unvaccinated Populations During the 2009 H1N1 Influenza Pandemic*, 104 AM. J. PUBLIC HEALTH 696, 696-701 (2014)); (5) [ECF 25-10] DeStefano et al., *Principal Controversies in Vaccine Safety in the United States*, 69 CLIN. INFECT. DIS. 1, 4 (2019)) ("DeStefano"); and (6) [ECF 25-12] R. Baxter et al., *Lack of Association of Guillain-Barré Syndrome with Vaccinations*, 57 CLIN. INFECT. DIS. 197-204 (2013)) ("Baxter").

[13] Dr. Collins cited [ECF 25-5] (C. Tam et al., *Guillain-Barré Syndrome and Preceding Infection with Campylobacter, Influenza and Epstein-Barr Virus in the General Practice Research Database*, 2 PLoS One 1, 5 (2007)) ("Tam").

> [T]the investigators found positive associations between [GBS] and a variety of infections including "acute respiratory infections" in the previous two months. Presumably due to prevention of influenza virus infection, the authors also found what appeared to be a protective effect of influenza vaccination . . . . In sum, these studies support the conclusion that infection rather than influenza vaccination is a risk factor for the development of [GBS].

[ECF 25-1] at 10. She then stated, citing a 2012 study of the relationship between GBS and a recent *H. influenzae* infection in thirty-five hospitalized Iranian patients, that "[t]here is substantial evidence that [*H. influenzae*], which was cultured from Mr. White's lungs on December 14, 2017, is one of the pathogens causing acute respiratory infections that increase risk for the development of [GBS]." *Id.*[14] Dr. Collins concluded:

> Based on the exhibits provided, and a thorough review of modern literature, there is strong evidence that infection, including acute respiratory infection, increases the risk of [GBS]. Mr. White experienced an acute respiratory infection with a ten-day history of symptoms prior to the development of his neurological symptoms. He had an elevated white blood cell count, an abnormal chest x-ray and infection by a bacterial pathogen ([*H. influenza*]) that causes respiratory infections and has been associated with [GBS]. In contrast, there is a strong and growing body of evidence that influenza vaccination is unlikely to increase risk of acquiring [GBS].

Id.

2. Althen Prong One

White argues that the CSM failed to mandate that the government satisfy its burden of proof under the first *Althen* prong by providing preponderant evidence of the biological mechanism by which *H. influenzae* could cause GBS. [ECF 36] at 25, 28. White states:

> If this is the standard to show "factor unrelated" without meeting all of the *Althen* prongs, then the higher burden pursuant to Federal Circuit decisions, has no meaning. Boiled down to its essence, the standard as articulated in the Decision, will simply be met with nothing more than literature and an expert concluding that the alternative has more risk of causing the GBS than the vaccine, which is in most cases.

[14] Dr. Collins cited [ECF 25-22] (S. Nafissi et al., *The Role of Cytomegalovirus, Haemophilus Influenzae and Epstein Barr Virus in Guillain Barre Syndrome*, 51 ACTA MEDICA IRANICA 372, 375 (2013)) ("Nafissi").

Id. at 28-29. White further avers: "Indeed, in addition to no explanation, no immunologist was proffered to address the issue. Nor, did respondent eliminate the vaccine as a substantial cause as required." *Id.* at 30.

Under the first *Althen* prong, the government must provide a medical theory causally connecting the factor unrelated to the flu vaccine and White's injury. In other words, the government must provide a medical theory causally connecting White's *H. influenzae* infection and his GBS. Although the government "must provide a reputable medical or scientific explanation that pertains specifically to [its] case," the explanation does not need to be "medically or scientifically certain." *Broekelschen*, 618 F.3d at 1345. It only needs to be "legally probable." *Id.* (quoting *Knudsen*, 35 F.3d at 548-49) (internal quotation marks omitted). Moreover, "conclusive evidence in the medical literature" is not required. *Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1378 (Fed. Cir. 2009); *see also id.* at 1379 ("[A] paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery.").

Here, the CSM evaluated and weighed the evidence to reach the conclusion that the government satisfied the first *Althen* prong. *See White*, 2023 WL 4204568, at *1, 17. He determined that a factor unrelated to the vaccine—an *H. influenzae* infection—was more likely the sole substantial cause of White's GBS. *Id.* The CSM appropriately based his determination on the medical literature,[15] the reports of the parties' expert witnesses, and his own experience as a special master. *See Saxton By & Through Saxton v. Sec'y of Dep't of Health & Hum. Servs.*, 3 F.3d 1517, 1521 (Fed. Cir. 1993) ("Vaccine program special masters are also entitled to use their prior experience in reviewing fee applications.").

In support of his contention that "there is reliable evidence in the medical literature demonstrating an association between the risk of GBS following infection generally," the CSM credited Dr. Collins' expert reports. *White*, 2023 WL 4204568, at *17. First, in his overview of the parties' expert reports, the CSM noted that although Dr. Collins "acknowledged that GBS attributable to the flu vaccine . . . is an accepted Vaccine Injury Table claim," she then found that "numerous studies have examined the risk of GBS following receipt of the vaccine, with results demonstrating that the risk is significantly less than that following an acute respiratory infection." *Id.* at *6. Next, the CSM noted that "[o]ther evidence of the infection/GBS association was referenced by Dr. Collins and deemed equally reliable and persuasive." *Id.* In his analysis, the CSM cited five medical papers proffered by Dr. Collins. The CSM cited: (1) Tam; (2) [ECF 25-16] (P. van Doorn et al, *Clinical Features, Pathogenesis, and Treatment of Guillain-Barre Syndrome*, 7 LANCET 939, 941 (2008)) ("van Doorn");[16] (3) [ECF 25-20] (Y.Y. Ju et al., *Haemophilus Influenzae as a Possible Cause of Guillain-Barré Syndrome*, 149 J. NEUROIMMUNOLOGY 160, 160 (2004)) ("Ju"); (4) [ECF 25-21] (M. Mori et al., *Haemophilus Influenzae Infection and Guillain-Barré Syndrome*, 123 BRAIN 2171, 2171 (2000)) ("Mori"); and

[15] Regarding his approach towards medical literature, the CSM explained that while he considered all the medical and scientific literature before him, he only referenced those articles relevant to his determination and/or central to White's case. *White*, 2023 WL 4204568, at *14.

[16] The CSM mistakenly refers to van Doorn as "van Doom." *Compare White*, 2023 WL 4204568, at *17 *with* [ECF 25-16] at 1.

(5) Nafissi. Each of these studies supports the CSM's finding of an association between infection generally and GBS.[17]

Next, the CSM observed that "[s]ome of the evidence is in fact specific to *H. influenza* infection." W*hite*, 2023 WL 4204568, at *17. In support of this contention, the CSM cited Ju,[18] one of the studies Dr. Collins credited in her expert report. *See* [ECF 25-1] at 10. Additionally, the CSM observed that White's expert, Dr. Steinman, "himself agreed to this association, even if he downplayed it a bit." W*hite*, 2023 WL 4204568, at *17 (citing [ECF 22-1] at 9). Further, the CSM noted: "And though Dr. Steinman cites literature that also associates vaccination and GBS, that risk is *consistently* deemed lesser in comparison (and in some studies unfounded)." W*hite*, 2023 WL 4204568, at *17 (emphasis in original). Here, the CSM cited DeStefano,[19] another study referenced by Dr. Collins. *See* [ECF 25-1] at 8 ("Influenza infection is a stronger risk factor for GBS than is influenza vaccine; thus, during an entire influenza season, influenza vaccination has been shown to actually decrease the risk of GBS by protecting against influenza infection.") (quoting DeStefano at 4) (internal quotation marks omitted). The CSM also noted, citing two of the studies discussed at length by Dr. Collins,[20] that "[i]t has even been documented that vaccination might play a protective role against GBS." W*hite*, 2023 WL 4204568, at *17 (citing Stowe at 385-86, Grimaldi-Bensouda at 326).

Lastly, in response to White's argument that the government's proof of causation is insufficient because it is based on "the contention that probabilities favor infection over vaccine, without much scientific showing," the CSM explained that "no one kind of evidence is needed to prove any of the *Althen* prongs," and that, in his experience, it is "almost beyond dispute that a *wide variety of infections*, both viral and bacterial, can likely be *as* causal, if not more, of GBS than the flu vaccine." W*hite*, 2023 WL 4204568, at *17 (emphasis in original). The CSM added that Dr. Steinman's evidence regarding the causal connection between the flu vaccine and GBS "*expressly notes* the causal capacity of infections." *Id.* (citing Ju at 166) (emphasis in original). The CSM stated: "This is actually the bedrock of many a vaccine claim: if infection can be causal, the infection-like response vaccines elicit could logically be causal as well." *Id.*

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[17] In Tam, the authors discuss a study of cases from a United Kingdom database between 1991 and 2001 for associations between GBS and infection with, among other things, influenza-like illness ("ILI") in the previous two months. Tam at 1. The authors note "strong, positive associations between infection with . . . ILI and GBS risk," as well as "evidence for an 18-fold increased risk of GBS in the two months following ILI." *Id.* at 5. In van Doorn, the authors note that "[m]olecular mimicry and cross-reactive immune responses have also been identified after some types of preceding infection, including *H influenzae*." van Doorn at 3. In Ju, the authors discuss "the frequency of infection as indicated by elevated antibody in GBS patients," and conclude that "although GBS is rarely preceded by *H. influenzae* in the UK, there is a probable rare association with certain strains of nonencapsulated *H. influenzae*." Ju at 6-7. In Mori, the authors "concluded that a form of [GBS] occurs after respiratory infection by *H. influenzae* in the Japanese population." Mori at 1. Lastly, in Nafissi, the authors studied the relationship between several infections and GBS and found that "only *Haemophilus influenzae* infection appeared to be significantly related to GBS." Nafissi at 372.

[18] *White*, 2023 WL 4204568, at *17 (citing Ju at 160).

[19] *White*, 2023 WL 4204568, at *17 (citing DeStefano at 4).

[20] *See* [ECF 25-1] at 6-7.

In sum, as to the first *Althen* prong,[21] the Court finds that the CSM's finding that *H. influenzae* was "preponderantly shown to likely be causal of GBS," was appropriately based on the evidence, which included both parties expert witness reports, the medical literature cited therein, and the CSM's own experience. His conclusion was in accordance with the law.

3. Althen Prong Three

White argues that the CSM improperly determined that the government satisfied its burden of proof under the third *Althen* prong. [ECF 36] at 31. First, White contends that "the CSM erroneously found that the GBS manifested after [White's] *likely* infection was medically acceptable i.e. 10 days before [his] neurologic symptoms on December 10, 2017." *Id.* at 31-32 (emphasis in original). White states that, not only did the CSM incorrectly find that White's GBS weakness started ten rather than seven days after his head cold, but the CSM could not have decided whether there was an appropriate temporal association between *H. influenzae* and GBS because the government's expert did not address the biological mechanism by which the infection causes GBS. *Id.* at 32. Next, White avers that the CSM was overly reliant on the literature referenced by the government's expert in support of his conclusion that the risk of GBS following an *H. influenzae* infection was greater than that following a flu vaccination. *Id.* at 34-35. Finally, White argues that the CSM erroneously found that the government proved that the *H. influenzae* infection was the sole and substantial cause of White's GBS. *Id.* at 35-36.

Under the third *Althen* prong, the government must demonstrate by preponderant evidence a proximate temporal relationship between a factor unrelated to the flu vaccine and White's injury. *See Althen*, 418 F.3d at 1278. In other words, the government must show a proximate temporal relationship between White's *H. influenzae* infection and his GBS. As noted above, the government's burden is higher than White's because the government must demonstrate that his *H. influenzae* infection was the *sole* substantial cause of his GBS. *See de Bazan*, 539 F.3d at 1354.

Here, the CSM appropriately evaluated and weighed White's medical records, the caselaw, and parties' expert witness reports to reach the conclusion that the government satisfied the third *Althen* prong. First, in support of his conclusion that "the timeframe in which [White's] GBS manifested after his likely infection was medically acceptable," the CSM stated: "The medical records establish that the infection (which first manifested 10 days before Petitioner's neurologic symptoms on December 10, 2017) occurred far closer in time than vaccination—but

[21] Although White does not challenge the CSM's conclusion under the second *Althen* prong, the Court notes that the CSM appropriately evaluated and weighed the evidence to reach the conclusion that White's "*H. influenza* infection likely 'did cause' his GBS." W*hite*, 2023 WL 4204568, at *17. First, the CSM noted that the medical records showed that White "experienced a URI with a ten-day history of symptoms," *id.*, that White's treaters consistently associated his infection with GBS, and that White's infection "predated neurologic symptoms onset," *id.* Addressing Dr. Steinman's concern "that the lack of blood testing confirmation reduced the likelihood of an infectious cause," the CSM noted that he was persuaded by the explanation proffered by Dr. Collins, an expert in infectious diseases. *Id.* According to the CSM, Dr. Collins "persuasively explained that a positive blood culture is unnecessary to confirm the presence of an *H. influenza* infection and in fact would not be expected unless the infection has spread to his blood." *Id.* (citing [ECF 25-1] at 11). Further, the CSM noted that White's sputum findings were positive for infection and that his chest X-ray and other test results supported his pneumonia diagnosis. *Id.* (citing [ECF 6-1] at 27-28 (12/14/2017 ICU lab results)); *id.* (citing [ECF 6-1] at 451 (12/14/2017 ICU x-ray results)).

within a timeframe that would be reasonable for an antibody-driven, adaptive immune system autoimmune process to occur."[22] *White*, 2023 WL 4204568, at *18. The CSM then cited *Randolph v. Secretary of Health and Human Services*, a decision wherein the Special Master determined that a twelve-day timeframe was a medically accepted period for how long it would take an infection to produce an adaptive immune response. *Id.* (citing 2021 WL 5816271, at *23 (Fed. Cl. Spec. Mstr. Nov. 12, 2021)). The CSM further credited White's medical record as adding "heft to the conclusion that the vaccine could likely be excluded as causal," noting that there was no evidence that White had a "close-in-time vaccine reaction," that White didn't seek medical treatment for his infectious symptoms until five weeks later, and that White's neurologic symptoms manifested five days after he first sought treatment. *White*, 2023 WL 4204568, at *18.

The CSM also appropriately noted that the fact that White experienced symptoms within the timeframe set forth in the Table is not ultimately dispositive as to causation. *White*, 2023 WL 4204568, at *18. *See Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1078 (Fed. Cir. 2020) (petitioners who assert on-Table claims are "afforded a *presumption* of causation") (emphasis added). Explaining his disagreement with Dr. Steinman's contention "that the very fact that the flu vaccine's causality is reflected in the existence of a Table claim somehow elevates the strength of reliability of the vaccine-injury association," the CSM stated:

> At most, the Table claim only substantiates the idea that the flu vaccine "can cause" GBS. It does not prevent my determination that (a) infections can also cause GBS, (b) H. influenza can cause GBS, (c) infections are more likely than vaccines to cause GBS, and (d) [White's] medical history lends strong support to the conclusion that the flu vaccine was not likely a factor in his GBS, whereas the intervening infection was.

Id.

Notably, the CSM also addressed whether the evidence demonstrated that both the flu vaccine and the *H. influenzae* infection caused White's GBS. *White*, 2023 WL 4204568, at *18. While acknowledging that, under *Shyface*, a petitioner may prevail if the government fails to satisfy its burden by showing an alternative cause, the CSM found that the government made the necessary showing in this case. *Id.* In so doing, the CSM not only credited Dr. Collins' conclusion that the evidence supported a finding that White's infection rather than his vaccine was the "but for" cause of his GBS, but he also found that Dr. Steinman's contrary assertions were conclusory and failed "to address the compelling record evidence that [White] was likely experiencing a pre-GBS onset sickness that could have been causal." *Id.* at *19. In sum, as to the third *Althen* prong, the Court finds that the CSM's conclusion that *H. influenzae* was the sole substantial cause of White's GBS was in accordance with the law.

[22] White's medical records support the CSM's finding that White experienced a URI ten days before he was admitted to the ED on December 10, 2017. *See* [ECF 6-1] at 200 (ICU notes taken by Dr. Kwon noting that White had a "bad URI 10 days prior to presentation"); *id.* at 205 (ICU notes taken by Dr. Burkhart noting that White "presented to the emergency department with complaints of 10-day history of viral URI with onset of bilateral lower extremity weakness on 12/10").

4. Weighing of the Evidence

In addition to arguing that the government failed to satisfy the first and third *Althen* prongs, White also argues that the CSM improperly gave "considerable weight . . . to Respondent's expert's literature and argument that the H. Influenza had more risk to cause GBS," whereas "the risk from vaccination was routinely deemed lesser." [ECF 36] at 34. The CSM did not, however, determine that the government had met its burden based on statistical probabilities alone. Instead, the CSM found that the government met its burden because the medical literature, the expert testimony, and the clinical records support the conclusion that White's *H. influenzae* infection was the sole substantial cause of his GBS and because the facts in this case support the conclusion that the vaccine did not play a contributory role in White's GBS. The CSM explained:

> The same record also adds heft to the conclusion that the vaccine could likely be excluded as causal. As noted above, there is no record evidence of any close-in-time vaccine reaction. Almost five weeks thereafter passed before Petitioner first sought treatment for his infectious symptoms, which by this point were already ongoing. And then five more days elapsed before Petitioner's neurologic symptoms onset. This medical history is not consistent with the vaccine playing even a contributory role to Petitioner's GBS. And the mere fact that his onset fell into the temporal period set for onset under a Table claim (albeit on one extreme end of that timeframe) does not guarantee a vaccine "role," right to the end. The facts of this case tell a different story, and one that excludes the vaccine as likely causal in any way.

White, 2023 WL 4204568, at *18. The Court cannot conclude that the CSM's weighing of the evidence was not in accordance with the law.

V. CONCLUSION

White has not demonstrated that the CSM's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Therefore, this Court must sustain the CSM's decision. White's motion for review of the CSM's decision is **DENIED**, and the CSM's entitlement decision of June 2, 2023, is **SUSTAINED**. The Clerk of the Court is **DIRECTED** to enter judgment accordingly.

IT IS SO ORDERED.

s/ Thompson M. Dietz
THOMPSON M. DIETZ, Judge